



Productivity Commission Draft Research Report Standard Setting and Laboratory Accreditation Supplementary Submission from NATA 1 September 2006

Summary

NATA acknowledges the Productivity Commission's Draft Research Report and its findings and draft recommendations. The Association is particularly reassured by the Commission's findings in regard to effectiveness, the significance of NATA's involvement with government, the importance of development and maintenance of international links for national and international credibility, and the need to more fully reflect NATA's public and national benefit roles in the Memorandum of Understanding between the Australian Government and NATA.

NATA also welcomes the Commission's detailed interest in proficiency testing matters and their significance.

The Association does, however, have concerns on some issues raised in the report on matters such as:

- The levels of future funding support for NATA's international engagement and representation of Australia's interests in ILAC, APLAC and ISO;
- Awareness and acknowledgement of the comprehensive public benefit of NATA's activities: and
- Apparent misunderstandings of the interactions of NATA's proficiency testing activities with other parties and practicalities associated with some of the draft recommendations and commentary in the report on proficiency testing matters.

NATA is pleased to now have the opportunity to respond to the draft report and seeks to clarify its views on the above issues through this supplementary submission. The opportunity is also being taken to comment on some other matters in the report and to identify some minor factual errors in the text.

Public Benefit

In its initial submission NATA attempted to highlight that its purpose for existence historically and currently is to provide a national service for the benefit of the Australian community at large. While NATA's *direct* clients are its accredited facilities, the objectives of its laboratory and other accreditation activities are intended to provide community confidence in the competence of bodies whose data affects decisions made across the whole gamut of Australian society. This includes decisions made by regulators, by purchasers and specifiers

(both public and private) and includes considerable public benefit outcomes in terms of, for example, public health, environmental protection etc.

In several instances in the Commission's draft report, reference is made to the private benefit gained by NATA itself and its accredited facilities for various activities, including its international engagements. This has led to proposals for significant funding reductions and also to complications in NATA's proposed roles for national coordination of proficiency testing.

Before commenting on specific recommendations in the report, NATA considers it is essential to highlight again that its fundamental purpose is one of public benefit. Even in terms of NATA's direct clients, the public sector itself is very highly represented. Approximately 24% of NATA's accredited facilities are in the public sector, and their scopes of accreditation comprise 31% of the total number of accredited technical units in the NATA system. This not only provides the public sector bodies themselves with confidence in their competence, but also the community at large can be reassured that governments' functions, that may affect their daily lives, are independently appraised for their competence through the NATA process. Again, in NATA's involvement in the accreditation of pathology laboratories (whose accreditations also cover almost one third of technical units in the NATA system), there are both community health benefits at large plus reassurance that taxpayers' funding of Medicare benefits is partially underpinned by that accreditation process. Numerous other examples could be cited of the public at large being the ultimate beneficiaries of the accreditation process.

Draft Recommendations

NATA has the following comments on each of the report's draft recommendations:

Draft Recommendation 12.1

The Australian Government should more rigorously progress the mutual recognition of conformance assessment in multilateral and bilateral fora. Similarly, NATA should continue to build on its voluntary mutual recognition arrangements.

NATA fully supports this recommendation and seeks continuing comprehensive Government funding support *at current levels* for its engagement in the fora needed to maintain and build such arrangements.

Draft Recommendation 12.2

Regardless of the action of other countries, the Australian Government should continue to progress recognition of accredited overseas test results for the purposes of regulation. Only when serious public health risks are involved or where clearly established concerns exist about a country's accreditation capacity, should the Australian Government rely exclusively on NATA, AQIS or TGA accreditation.

NATA fully supports this recommendation, but suggests that the word "accreditation" at the end of the text might better be replaced by "recognition".

Draft Recommendation 12.3

NATA should ensure that the extent and design of proficiency testing are adequate through more extensive discussions with all stakeholders, including customers of laboratory services. This may include greater customer representation on NATA's Accreditation Advisory Committees or the establishment of a committee advising on appropriate proficiency testing requirements.

NATA believes this recommendation is basically sound and is in line generally with NATA's historical and proposed future practice. Each proficiency test is a project in its own right. For programs previously conducted by NATA itself, but now conducted by Proficiency Testing Australia (PTA), an external expert or experts are appointed to advise on the technical details of specific programs and to diagnose the outcomes. NATA no longer undertakes proficiency testing, but PTA will itself be expected to continue to have ongoing and appropriate technical advice for its programs to both satisfy NATA (and its Accreditation Advisory Committees) and the requirements of the overseas body which separately accredits PTA.

With regard to extent and adequacy of proficiency testing and consultation with external stakeholders, NATA notes the comprehensive inputs on this topic from the WSAA submission but has significant concerns about some elements and perceptions conveyed in that submission which impact on this issue. NATA would welcome the opportunity to discuss those issues in more detail with the Commission.

In terms of specific customer inputs to proficiency testing activities, NATA already welcomes such inputs (including from those on its Accreditation Advisory Committees). New inputs are also welcomed as, for example, suggested to a technical representative of WSAA earlier this year, that his organisation might seek to be included on an appropriate NATA committee. We await such a request from WSAA.

NATA does already have a Proficiency Testing Providers Accreditation Advisory Committee comprising eminent specialists.

Draft Recommendation 12.4

NATA should actively promote a more competitive proficiency testing services market. NATA should assume more of a coordinating role in the provision of proficiency testing services for laboratory accreditation purposes including by:

- ***publicly detailing the criteria for the selection of proficiency testing programs necessary for accreditation; and***
- ***requiring accredited laboratories to inform NATA of the results of such specified tests in order to maintain accreditation.***

NATA is receptive to both the dot point issues above, but has reservations about its ability to promote a more competitive proficiency testing services market.

Availability of proficiency testing resources in Australia is already scarce. See, for example the WSAA submission on the availability of water testing proficiency testing services, where NATA is already covering a market failure in domestic availability of comprehensive proficiency testing, by conducting the vast bulk of water programs at present. (In this specific sector NATA has on a number of occasions supported the concept of establishing a coordinating committee as proposed by WSAA and still awaits some action on this). Most of the areas where NATA (and now Proficiency Testing Australia) are active are not commercially attractive. This situation is also likely for future additional proficiency testing programs and particularly in sectors where there are small groups of laboratories.

NATA's ability to coordinate the provision of proficiency testing activities would be assisted greatly, however, if the Commission reviewed its willingness to endorse NATA's request to have such a national role highlighted in the MOU with the Commonwealth. This acknowledgement would also assist greatly in NATA's participation in the ILAC and ISO fora dealing with international recognition of proficiency testing providers. In this regard NATA is currently chairing ILAC's Proficiency Testing Consultative Group, which is attempting to achieve international harmonisation and recognition of proficiency testing providers, possibly through extensions to the existing ILAC MRA. In that context also NATA is concerned that the concept of *certification* of proficiency testing providers would be considered as an alternative to the competence recognition provided by *accreditation* of such providers. Demonstrated

technical competence, rather than management systems compliance, is crucial if proficiency testing is to be used by accreditation bodies.

Draft Recommendation 12.5

NATA should ensure and be able to demonstrate that its proficiency testing subsidiary is operated at arms length and not given favourable treatment or inappropriate referrals vis-à-vis competitors.

NATA considers this has already been done. In regard to competitors there is very limited overlap between PTA's proficiency testing and other accredited proficiency testing providers in Australia. In this context, NATA has separately provided the Commission with a full listing of the hundreds of proficiency testing programs operated by NATA (and now PTA) and the scopes of accreditation of other PT providers. This clearly demonstrates the limited overlap that exists.

Draft Recommendation 12.6

A formal detailed complaints handling process should be established by NATA to deal with any complaints arising from NATA's proficiency testing requirements for laboratory accreditation and the conduct of its own, or its subsidiary's proficiency testing programs.

NATA is surprised to see this recommendation, as it already has a very comprehensive complaints handling process, which includes detailed investigation and resolution of the few complaints received about proficiency testing over recent years. Additionally, the draft recommendation refers to NATA's conduct of proficiency testing, but NATA itself ceased conducting its own on 31 December 2005.

NATA is advised that its subsidiary also has its own complaints handling procedure and since establishment of Proficiency Testing Australia has received 2 complaints. Incidentally, given the criticisms of proficiency testing in the WSAA submission, NATA is concerned that no specific details of specific complaints have been received from WSAA or its members over recent years apart from one informal and indirect complaint that NATA's proficiency testing requirements for *Cryptosporidium* were too demanding.

Draft Recommendation 12.7

The Australian Government should not proceed with the imposition of mandatory NATA accreditation in the radiology area until a comprehensive, Government-initiated review of its costs and benefits, as well as an assessment of alternative forms of accreditation, has been undertaken.

NATA's involvement with radiology accreditation has not been discussed with the Commission to date, including the costs and benefits, which are essentially the same as in the other areas of accreditation conducted by NATA, including pathology. NATA would welcome an opportunity to discuss this issue in detail with the Commission.

Draft Recommendation 13.1

The Australian Government should continue to recognise NATA as Australia's non-government national authority for the accreditation of laboratories and certified reference material suppliers and as the peak authority for the accreditation of inspection bodies.

NATA welcomes this recommendation. As discussed under Draft Recommendation 12.4, NATA asks that reconsideration be given to NATA's request to have its accreditation of

Proficiency Testing Providers also included in the recommendation and in the text of the MOU with the Commonwealth.

Editorially, it is suggested also that *reference material suppliers* be replaced by *reference material producers* as this is the correct terminology for NATA's accreditation activities in this area.

Draft Recommendation 13.2

The Australian Government's funding to NATA should be allocated only to areas with clear public benefits. Future Government grants should:

- ***fund the costs of NATA's involvement in the OECD Panel on Good Laboratory Practice and its participation in mutual recognition evaluations;***
- ***partially fund the costs associated with NATA's involvement in ILAC, APLAC and relevant ISO/IEC Committees; and***
- ***provide funding for special projects which NATA undertakes directly for the Australian Government, such as involvement in international negotiations.***

The Australian Government should not underwrite proficiency testing undertaken by NATA, or its subsidiary, unless it can be robustly demonstrated that in specifically identified areas such testing is in the public interest and that it is not commercially viable.

In terms of this draft recommendation, NATA is concerned about the proposed limitations placed on future funding for proficiency testing but anticipates identifying programs considered to be in the public interest and non-commercially viable.

The proposed continued funding of OECD representation and participation in MRA evaluations is acknowledged.

NATA is very concerned, however, by the proposed reduction in Government support for NATA's representation in ILAC, APLAC and ISO. In this context NATA notes, firstly, that the purpose of such involvements is essentially in the national interest and reinforces the opportunity for NATA to build further on its voluntary mutual recognition arrangements as proposed in the Commission's draft recommendation 12.2.

Additionally, NATA's involvement in ILAC and APLAC and relevant ISO/IEC Committees is one of the commitments for NATA to undertake in its MOU, on behalf of Australia, not NATA. Further, the funding received is already discounted from the full cost of undertaking these activities as NATA already partially funds the full costs of servicing them.

The formula proposed for reduced funding will inevitably lead to an erosion of the traditional influence and respect for Australia's testing and measurement capability amongst our counterparts internationally.

NATA appreciates the Productivity Commission's recognition that NATA's international activities serve the national interest and the public interest. Earlier in this submission we restate our view that our overriding role is one of public interest. In acknowledging the Commission's recommendation that the Australian Government should continue to fund NATA's participation in mutual recognition arrangement (MRA) evaluations, we do, however, wish to present the rationale for full funding for NATA's involvement in all ILAC and APLAC activities.

To be accepted as a signatory to the APLAC Mutual Recognition Arrangement (MRA) and global ILAC Arrangement, and to participate in MRA evaluations, NATA has first to be a member of each organisation and pay membership fees. Payment of these annual

membership fees is, therefore, integral to NATA's involvement in MRA evaluations. As a signatory to the APLAC MRA and ILAC Arrangement NATA has taken on certain obligations that are spelt out in the MRA texts. These obligations include:

- to contribute to the work of the APLAC MRA Council (APLAC MRA text)
- to contribute to the work of the ILAC Arrangement Council (ILAC Arrangement text)

These two bodies meet twice a year and so NATA's attendance at these meetings is also integral to its involvement in MRA evaluations, and the deliberations on acceptance of new signatories and reaffirmation of existing signatories.

Integral to NATA's involvement in MRA evaluations is its ability to influence the criteria applied to accreditation bodies that are signatories to the MRAs, and the criteria applied to the signatories' accredited facilities. This influence is effected mainly through attendance at the relevant APLAC and ILAC technical meetings, but it also extends to the relevant ISO/IEC Standards and Guides which are underpinning these MRAs.

NATA also has influence, through the participation by NATA's senior staff, on the APLAC Board of Management (currently as Chair) and ILAC Executive, and by some other senior NATA staff on relevant APLAC and ILAC committees. This active participation, including attendance at meetings, is critical to Australia having an influence on criteria that impact directly on Australian laboratories and inspection bodies, and through them, on the Australian public interest being served by a capable national network of testing, measurement and inspection resources.

While it is accepted there is some benefit to NATA and the professional development of its staff in the various activities of APLAC and ILAC, participation is not for NATA per se, or singularly, for the NATA membership. NATA participates in these activities to ensure that, in an increasingly global market, Australia can have an assurance of the credibility of test, calibration and inspection results, from overseas facilities while also facilitating the international acceptance of Australian tests and measurements.

NATA therefore asks that draft recommendation 13.2 be reconsidered to maintain at current levels the future government grants associated with NATA's participation in APLAC, ILAC and relevant ISO/IEC activities.

Draft Recommendation 13.3

The Australian Government should continue to use the Memorandum of Understanding (MoU) as the principal means of setting out its relationship with NATA and, while it is basically sound, amendments are warranted including:

- ***NATA's obligations should be made clearer by better defining public interest activities, by an obligation to keep laboratory standards high while minimizing the fees it charges, and by an obligation to maintain and publicise a list of proficiency testing providers;***
- ***NATA should be required to publicly report annually on its performance in meeting the MoU obligations; and***
- ***Some other minor updates to reflect NATA's increasing role in service related industries; the establishment of the National Measurement Institute; the creation of a new NATA subsidiary, Proficiency Testing Australia and changes in some standards.***

NATA welcomes this recommendation, but asks for reconsideration of inclusion of the role of NATA in accreditation of Proficiency Testing Providers. In terms of publicly listing proficiency testing programs, NATA sees no issue in this apart from the need to carefully distinguish between accredited and non-accredited providers and a need to continue to acknowledge that such a listing of the latter group does not provide a NATA endorsement of their competence.

General Issues

In some parts of the draft report there are observations which appear to be theoretical or of potential, rather than actual findings. This might lead to some readers believing that the circumstances described are actual findings.

In particular, on page 199 the discussion appears to leave open, whether NATA's structure has led to reduction of standards "...to guarantee retainment of NATA accreditation..." and "...increasing the hurdles to attaining new membership, so as to lessen competitive pressures on laboratories on the inside...". NATA strenuously asserts this is not the case and asks whether the Commission found any evidence of such.

Similarly, the quotes from the WSAA statement on page 203 and that of the NSW Food Authority imply that NATA may be influenced, or be perceived to be influenced, by NATA's funding relationship with its direct clients. This also is absolutely untrue and, though qualified in both quotes, will either add to a false perception, or create such.

Editorial Issues

NATA has noted a few editorial errors in the draft report.

In particular:

- Page XXVII-3rd para should read "...relies heavily on biennial assessment..."
- Page 189 –second paragraph-4th line should read "...every three years..."
- Box 12.1 –4th dot point should read "...NSW Department of Primary Industries..."
- Page 205- last para- reference to ISO/IEC 17025 is for laboratories' compliance –not the accreditation bodies. Does the Commission mean ISO/IEC 17011?

Concluding Remarks

NATA has benefited from the close and constructive scrutiny of its operations and roles through this Research Study and now looks forward to the opportunity to add any further comments or responses that the Commission might require to successfully conclude its research.